

Questions for DODAC

1. Is the proposed set of decision rules for antifungal/corticosteroid combination topical products acceptable for documenting the contribution of both components?
2. Is the proposed set of products and indications for approval acceptable?
 - a. Can a distinction be made in labeling between “minimally inflamed tinea not requiring a corticosteroid component” and “sufficiently inflamed tinea warranting a corticosteroid component”? If so, suggest wording.
 - b. Is the knowledge (and corresponding labeling) that allows the claim that AF alone provides the antiinflammatory activity comparable to a CS a sufficient advance in public health to warrant a CS only arm?
 - c. Is it sufficient that the CS does not reduce the antifungal activity of (AF + CS) to label the product for all tinea or should combination products containing CS be labeled only for the more inflammatory tinea warranting antiinflammatory treatment?